Memo of Meeting

Date: December 6, 2001

Representing Daon, Co. of Dublin Ireland:

Oliver Tattan, Chief Executive Officer
Stephen Loughman, FIA, VP Business Development
Conor White, Chief Technical Officer
Martin Walsh, VP Regulatory Affairs

Representing FDA:

Charles A. Snipes, Compliance Officer, Center For Drug Evaluation and Research
Mark H. Hackman, Consumer Safety Officer, Center For Food Safety & Applied Nutrition
Paul J. Motise, Consumer Safety Officer, Office of Regulatory Affairs

The meeting was held at the request of the Daon representatives, to discuss their electronic identity product in the context of 21 CFR Part 11. At the start of the meeting we explained that FDA does not formally review, approve or disapprove of products or services that enable people to comply with FDA regulations. We advised that the meeting would be an information exchange and that our comments should not be taken as formal FDA positions.

The Daon representatives explained that the privately held company produces an electronic identity product that was designed from he ground up with part 11 requirements in mind and initially focused on the pharmaceutical industry. The firm's system provides a biometric based front end to digital signatures and public key infrastructures (PKIs). Initially, the biometric trait will be fingerprints, with other traits to be folded into the product in the future. The biometric input is not backed up with identification code and password methods of authentication.

We discussed the product's biometric system false accept and false reject rates and adaptation to existing PKI systems. Individuals would have to be enrolled into the biometric system, but companies have the option of retaining employee PKI key pairs or establishing new ones.

The product is designed for scaleable application to computer platforms including Windows and Unix. During the meeting the representatives explained the technologies of their system and the general methods of integration into a PKI. They also addressed the benefits of their approach and the relative cost savings

compared to other technologies; they commented that customers should realize an approximate 6 or 7 to one return on investment.

During the meeting we discussed the firm's validation efforts. The representatives said they would welcome customer audits of their software development activities.

The meeting lasted about two hours.

cc:
FDA Attendees
HFA-224
Part 11 Guidance Dockets

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P. Motise 12/21/01